

K071037  
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## 510(k) Summary

**Trade Name:** SPY® Intra-operative Imaging System

**Model Number:** SP2000

MAY 10 2007

**Common Name:** Fluorescent Angiographic System

**Classification:** 21 CFR 892.1600

**Product Code:** 90 IZI

**Classification:** Class II

**Manufacturer:** Novadaq® Technologies Inc.  
2585 Skymark Avenue  
Suite 306  
Mississauga, Ontario  
Canada  
L4W 4L5  
905.629.3822 ext. 240

**Contact Name:** Allison Manners  
Vice President – Regulatory and Clinical Affairs

**Date 510(k) Summary Prepared:** April 9, 2007

### Legally Marketed Predicate Devices:

The Novadaq SPY Imaging System had received FDA 510(k) clearance for market in January 2005 (K042961) and subsequently received 510(k) clearance for a labeling change in May 2006 (K060867).

### Device Description:

The SPY Imaging System: SP2000 is currently cleared for use for intra-operative visual assessment of the coronary vasculature and grafts during coronary artery bypass graft (CABG) surgery.

The Novadaq Technologies SPY Intra-operative Imaging System consists of 2 components:

- the SPY Imaging Device; and
- the SPY Paq®



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 10 2007

Ms. Allison Manners  
Vice President, Regulatory and Clinical Affairs  
Novadaq Technologies Inc.  
2585 Skymark Avenue Suite 306  
Mississauga, Ontario Canada L4W 4L5

Re: K071037  
Trade Name: SPY® Intraoperative Imaging System  
Regulation Number: 21 CFR 892.1600  
Regulation Name: Angiographic X-Ray System  
Regulatory Class: Class II (two)  
Product Code: IZI  
Dated: April 11, 2007  
Received: April 12, 2007

Dear Ms. Manners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may not market this device, however, until such time as the new drug application for the drug indocyanine green manufactured by PULSION® Medical Systems is approved for human use by The Center for Drug Evaluation and Research, FDA. When the device is marketed, it will be subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

However, you are responsible to determine that the medical devices you use as components in the SPY® Intraoperative Imaging System have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the Act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments.

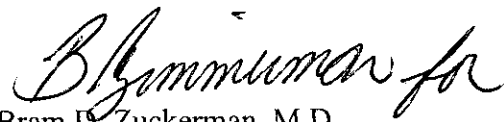
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification subject to approval of the indocyanine green manufactured by PULSION® Medical Systems. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

## Indications for Use

510(k) Number (if known): K071037

Device Name: SPY® Intra-operative Imaging System: SP2000

### Indications for Use:

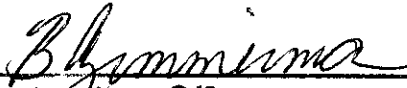
For use in intraoperative visual assessment of the coronary vasculature and bypass grafts during coronary artery bypass (CABG) surgery.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K071037

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